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- (4) The amount of the proposed penalty, assessment and the period of proposed exclusion (where applicable);
- (5) Any circumstances described in §1003.106 that were considered when determining the amount of the proposed penalty and assessment and the period of exclusion:
- (6) Instructions for responding to the notice, including—
- (i) A specific statement of respondent's right to a hearing, and
- (ii) A statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty, assessment and exclusion without right of appeal; and
- (7) In the case of a notice sent to a respondent who has an agreement under section 1866 of the Act, the notice also indicates that the imposition of an exclusion may result in the termination of the provider's agreement in accordance with section 1866(b)(2)(C) of the Act.
- (b) Any person upon whom the Inspector General has proposed the imposition of a penalty, assessment or exclusion may appeal such proposed penalty, assessment or exclusion to the DAB in accordance with §1005.2 of this chapter. The provisions of part 1005 of this chapter govern such appeals.
- (c) If the respondent fails, within the time permitted, to exercise his or her right to a hearing under this section, any exclusion, penalty, or assessment becomes final.

[57 FR 3348, Jan. 29, 1992, as amended at 59 FR 32126, June 22, 1994; 64 FR 39429, July 22, 1999; 65 FR 24418, Apr. 26, 2000]

§ 1003.110 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by §1003.109(a), the Inspector General may impose the proposed penalty, assessment, and exclusion, or any less severe penalty, assessment, and suspension. The Inspector General shall notify the respondent by certified mail, return receipt requested, of any penalty, assessment, and exclusion that has been imposed and of the means by which the respondent may satisfy the judgment. The respondent has no right to appeal a penalty, assessment, and exclusion,

with respect to which he or she has not requested a hearing.

[51 FR 34777, Sept. 30, 1986, as amended at 57 FR 3348, Jan. 29, 1992]

§ 1003.114 Collateral estoppel.

- (a) Where a final determination pertaining to the respondent's liability under §1003.102 has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent shall be bound by such determination in any proceeding under this part.
- (b) In a proceeding under this part that—
- (1) Is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements, and
- (2) Involves the same transactions as in the criminal action, the person is estopped from denying the essential elements of the criminal offense.

[57 FR 3348, Jan. 29, 1992, as amended at 64 FR 39429, July 22, 1999]

§ 1003.126 Settlement.

The Inspector General has exclusive authority to settle any issues or case, without consent of the ALJ.

[65 FR 24418, Apr. 26, 2000]

§ 1003.127 Judicial review.

Section 1128A(e) of the Act authorizes judicial review of a penalty, assessment or exclusion that has become final. Judicial review may be sought by a respondent only with respect to a penalty, assessment or exclusion with respect to which the respondent filed an exception under §1005.21(c) of this chapter unless the failure or neglect to urge such exception will be excused by the court in accordance with section 1128A(e) of the Act because of extraordinary circumstances.

[57 FR 3348, Jan. 29, 1992]

§ 1003.128 Collection of penalty and assessment.

(a) Once a determination by the Secretary has become final, collection of any penalty and assessment will be the responsibility of CMS, except in the case of the Maternal and Child Health

Services Block Grant program, where the collection will be the responsibility of the PHS, and in the case of the Social Services Block Grant program, where the collection will be the responsibility of the Office of Human Development Services.

- (b) A penalty or assessment imposed under this part may be compromised by the Inspector General, and may be recovered in a civil action brought in the United States district court for the district where the claim was presented, or where the respondent resides.
- (c) The amount of a penalty and assessment when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States, or by a State agency, to the respondent.
- (d) Matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

[51 FR 34777, Sept. 30, 1986, as amended at 57 FR 3349, Jan. 29, 1992; 65 FR 24418, Apr. 26, 2000]

§ 1003.129 Notice to other agencies.

Whenever a penalty, assessment or exclusion become final, the following organizations and entities will be notified about such action and the reasons for it—the appropriate State or local medical or professional association; the appropriate Quality Improvement Organization; as appropriate, the State agency responsible or the administration of each State health care program; the appropriate Medicare carrier or intermediary; the appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies); and the longterm care ombudsman. In cases involving exclusions, notice will also be given to the public of the exclusion and its effective date.

[57 FR 3349, Jan. 29, 1992]

§ 1003.132 Limitations.

No action under this part will be entertained unless commenced, in accordance with §1003.109(a) of this part,

within 6 years from the date on which the claim was presented, the request for payment was made, or the incident occurred.

[57 FR 3349, Jan. 29, 1992]

§ 1003.133 Statistical sampling.

- (a) In meeting the burden of proof set forth in \$1005.15, the Inspector General may introduce the results of a statistical sampling study as evidence of the number and amount of claims and/or requests for payment as described in \$1003.102 that were presented or caused to be presented by respondent. Such a statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, shall constitute prima facie evidence of the number and amount of claims or requests for payment as described in \$1003.102.
- (b) Once the Inspector General has made a prima facie case as described in paragraph (a) of this section, the burden of production shall shift to respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. The Inspector General will then be given the opportunity to rebut this evidence.

 $[51~{\rm FR}~34777,~{\rm Sept.}~30,~1986,~{\rm as~amended~at}~57~{\rm FR}~3349,~{\rm Jan.}~29,~1992]$

§ 1003.134 Effect of exclusion.

The effect of an exclusion will be as set forth in §1001.1901 of this chapter.

[57 FR 3349, Jan. 29, 1992]

§ 1003.135 Reinstatement.

A person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with the provisions of §§1001.3001 through 1001.3004 of this chapter.

[57 FR 3349, Jan. 29, 1992]